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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,823	03/18/2004	Shiv Srivastava	4995.0053-01	5907
22852 7590 06/04/2007 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER RAWLINGS, STEPHEN L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/802,823	Applicant(s) SRIVASTAVA ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11 and 18-35 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, 18-21 and 31-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20040318; 20040715</u> | 6) <input checked="" type="checkbox"/> Other: <u>IDS:20050201</u> |

DETAILED ACTION

1. The election with traverse filed March 7, 2007, is acknowledged and has been entered.

Applicant has elected the invention of Group XX, claims 22-30¹, drawn to a method of detecting a PCGEM1 nucleic acid in a biological sample.

2. Claims 6-11 and 18-35 are pending in the application. Claims 6-11, 18-21, and 31-35 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 7, 2007.

3. Claims 22-30 are currently under prosecution.

Election/Restrictions

4. Applicant's traversal of the propriety of the restriction and election requirement set forth in the Office action mailed January 17, 2007, is acknowledged.

Beginning at page 3 of the response filed March 7, 2007, Applicant has argued that the requirement is improper because the Examiner has not established that the inventions are independent or distinct, or that there would be a serious burden on the Examiner otherwise.

Applicant's argument has been carefully considered but not found persuasive for the following reason:

The Examiner disagrees with Applicant's assertion that the Examiner has failed to establish the propriety of the requirement in accordance with M.P.E.P. § 803. As

¹ Claim 31, which depends from claim 6, was inadvertently listed by the preceding Office action as a claim drawn to the elected invention; because claim 31 is directed to the subject matter of the non-elected invention, it has been withdrawn from further consideration during the prosecution of this application.

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explained in the preceding Office action the inventions are patentably distinct, each from the others, for the following reasons:

The inventions of Groups II-XIX are products, whereas the inventions of Groups I and XX are processes.

The inventions of Groups II-XIX and the inventions of Groups I and XX are unrelated because the products of Groups II-XIX are not specifically used or otherwise involved in the processes of Groups I and XX.

The inventions of Groups II-XIX are patentably distinct, each from the others, because each is a nucleic acid molecule consisting of, or comprising a distinct polynucleotide sequence.

As further explained, because of such differences, the search necessary to examine claims directed to any of the inventions of Groups II-XIX is not the same, nor is it coextensive with the search necessary to examine claims directed to any of the others. Accordingly, a separate and different search would have to be performed to examine claims directed to any one of these groups of inventions. Therefore, the examination of more than one of the inventions would constitute a serious burden.

Since the inventions of Groups II-XIX are patentably distinct, each from the others, and because the examination of more than one could not be made without serious burden, contrary to Applicant's argument, it is proper to restrict one from the other. See M.P.E.P. § 803.

Then, the preceding Office action further explained that the inventions of Groups I and IV are patentably, if not unrelated for the following reasons:

The inventions of Group I are processes for detecting prostate cancer, whereas the inventions of Group IV are processes for detecting a nucleic acid molecule in a biological sample; therefore, the inventions of Groups I and IV have different purposes or objectives. Because the inventions have different purposes or objectives, the different processes necessarily comprise different process steps. For example, these different processes may involve the acquisition of different samples from different sources (e.g., different populations of subjects or patients), as well as the measurement of different endpoints, and the establishment of different correlations between those

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endpoints. Moreover, the processes of the inventions of Group I necessarily involve the acquisition of a biological sample, and the correlation of a measured endpoint and the presence in the subject from which the sample was acquired of prostate cancer cells, whereas the processes of the inventions of Group IV do not. The inventions of Group IV simply measure the presence of PCGEM1 nucleic acid in a sample; it is either present or not, and the claims do not require the practitioner to detect the presence of prostate cancer. Furthermore, because the inventions of the different groups have different purposes or objectives, and involve the measurement of different endpoints and the establishment of different correlations, they necessarily have different criteria for success. For these reasons, the inventions of Groups I and IV are patentably distinct.

Because the inventions of Groups I and IV are distinct for these reasons, the search required to examine claims directed to any one of these inventions is not the same, nor is it coextensive with the search required to examine claims directed to any other. Furthermore, the inventions of Groups I and IV have acquired a separate status in the art, as evidenced by their art-recognized divergence in subject matter. Because different searches would have to be performed to examine claims directed to the inventions of Groups I and IV, an examination of both would constitute a serious burden.

Since the inventions of Groups I and IV have been shown to be patentably distinct, and because the examination of both could not be made without serious burden, it is proper to restrict each from the other. See M.P.E.P. § 803.

Applicant has remarked that they do not understand how the various different characteristics of the different inventions, which have been identified, establish that the inventions are patentably distinct, but given the above explanation, it is submitted that the reason is overt.

Applicant has remarked that the processes of Groups I and XX are related because the processes share a common step. If it is Applicant's position that any process sharing a common step with another is not patentably distinct for that reason, the Examiner strongly disagrees. Though the process of the inventions of Groups I and

XX may share the commonality of determining whether the nucleic acids to which the claims are directed hybridize, the processes are materially different, have different objectives or purposes, involve the measurement of different endpoints, involve the establishment of different correlations, and have markedly different criteria for success. It is, for example, a routine matter to determine if the transcript of the *PCGEM1* gene is present in a cell; it is not so routine to determine whether a subject has prostate cancer, even if that objective might be achieved by simply determining if *PCGEM1* is expressed in a sample of cells acquired from the subject.

In addition, it is aptly noted that the claimed process for detecting the presence of a PCGEM nucleic acid in a sample is not also a process for detecting the presence of prostate cancer. The gene is not exclusively expressed in prostate cancer cells; it is also expressed in normal prostate cells². Therefore, the mere presence of the transcript of the gene in a cell would not indicate the presence of prostate cancer.

Furthermore, contrary to the assertion set forth in the claims that the amount of the PCGEM1 nucleic acid in a biological sample correlates with the presence of prostate cancer, the specification paradoxically discloses that *PCGEM1* expression was not detected in certain prostate cancer cell lines, namely DU145, PC3, DuPro and CPDR, and concludes therefore that PCGEM1 may only be expressed by androgen-responsive cell lines, and not by androgen-independent cell lines³. It is submitted that this disclosure supports the Office's position that the inventions are patentably distinct for the reasons stated above because it suggests that one cannot necessarily detect prostate cancer by simply determining if the gene is expressed. Therefore, again, though the process of the inventions of Groups I and XX may share the commonality of determining whether the nucleic acids to which the claims are directed hybridize, the processes are necessarily involve the measurement of different endpoints, involve the establishment of different correlations, and have markedly different criteria for success.

² See, e.g., Srikantan et al. (*Proc. Natl. Acad. Sci. USA*. 2000 Oct 24; **97** (22): 12216-12221) (of record; cited by Applicant); see entire document (e.g., page 12219, Figure 4).

³ See the disclosure at, e.g., paragraph [0117] of the published application, U.S. Patent Application Publication No. 2004/0146932 A1.

Consequently, the prior art applicable to one invention would not likely be applicable to another invention, and the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Thus, the restriction set forth in the preceding Office action is deemed proper because each of the inventions is independent or distinct for the reasons given above and, if restriction were not required, there would be a serious search and examination burden.

Finally, as it is *might* be Applicant's position that the inventions are not patentably distinct, because each is related by the common inclusion of an active step of determining if the nucleic acid hybridize, Applicant should have submitted evidence, or at least identified such evidence, now of record, showing the inventions to be obvious variants, or clearly admit on the record that this is the case. Notably in either instance, then, were the Examiner to find one of the inventions unpatentable over the prior art, such evidence or admission could be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Accordingly, though Applicant's arguments have been carefully considered, the requirement is deemed proper and therefore made FINAL.

Information Disclosure Statement

5. The information disclosures filed March 18, 2004, July 15, 2004, and February 1, 2005, have been considered. An initialed copy of each is enclosed.

The "International Search Report", which is cited on the disclosure statement filed March 18, 2004, has not been considered because it is not evident to which document the disclosure refers. Moreover, it does not appear that copy of such a report was submitted, thereby failing to comply with the requirement set forth under 37 CFR 1.98(a)(2), which states that a legible copy of each cited document must be provided.

Drawings

6. Receipt of the replacement sheet for Figure 8 and a marked-up copy of a replacement sheet, including an annotation indicating the change made to the previous

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version, is acknowledged. The corrected sheet has replaced the errant sheet in this application.

Oath/Declaration

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a), along with the surcharge set forth in 37 C.F.R. § 1.16, is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention. More particularly, this application presents claims to processes, which were not claimed or adequately embraced by the statement of the invention in the earlier filed applications to which this application is related to satisfy the requirements set forth under 35 U.S.C. §§ 101 and/or 112, were the inventions to have been claimed in those prior applications. See 37 C.F.R. § 1.63.

The application should be redesignated as a continuation-in-part. See M.P.E.P. § 602.05(a).

Priority

8. Applicant's claim under 35 U.S.C. §§ 119(e) and/or 120, 121, or 365(c) for benefit of the earlier filing dates of Non-provisional Application No. 09/534,072, filed March 24, 2000, and Provisional Application No. 60/126,469, filed March 26, 1999, is acknowledged.

However, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §§ 120 as follows:

The disclosure of the prior-filed application, Application No. 09/534,072, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. More specifically,

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Application No. 09/534,072 fails to adequately describe the instantly claimed method of detecting a PCGEM1 nucleic acid in a biological sample.

Furthermore, claims 22-30 do not properly benefit under §§ 119 and/or 120 by the earlier filing dates of the priority documents claimed, since those claims are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure.

To receive benefit of the earlier filing date under §§ 119 and/or 120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). See M.P.E.P. § 201.11.

In addition, because the pendency of this provisional application expired March 26, 2000, the provisional application was not pending on the day that this application was filed. As such, this application cannot directly claim the benefit of the earlier filing date of the provisional application, as Applicant has done at page 1 of the specification, as amended, though notably Applicant may claim the benefit of Application No. 09/534,072, filed March 24, 2000, now issued as Patent No. 6,828,429, which claims benefit of U.S. Provisional Application No. 60/126,469, filed March 26, 1999.

Nonetheless, even were claims 22-30 otherwise adequately supported by the disclosure of Provisional Application No. 60/126,469, those claims would not properly benefit under §§ 119 and/or 120 by the earlier filing date of the provisional application because the claims are directed to a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1, which is not described by the provisional application⁴.

Accordingly, the effective filing date of the claims is deemed the filing date of the instant application, namely March 18, 2004.

Specification

9. The disclosure is objected to because the statement of continuity at page 1 of the specification, as amended, indicates that this application claims the benefit of U.S. Provisional Application No. 60/126,469, filed March 26, 1999. The pendency of this provisional application expired March 26, 2000; therefore, the provisional application was not pending on the day that this application was filed. As such, Applicant cannot directly claim the benefit of the earlier filing date of the provisional application, as has been done, though notably Applicant may claim the benefit of Application No. 09/534,072, filed March 24, 2000, now issued as Patent No. 6,828,429, which claims benefit of U.S. Provisional Application No. 60/126,469, filed March 26, 1999.

The statement of continuity should be appropriately amended to properly claim the benefit of the earlier filed applications; additionally, the statement should be amended to indicate the serial number of the patent issued on the prior filed application.

10. The disclosure is objected to because the statement of continuity improperly indicates this application is a continuation of prior filed Application No. 09/534,072. The specification and drawings filed in the continuation or divisional application contain no matter that would have been new matter in the prior application; yet, as explained in further detail below, this application presents claims to a processes, which were not claimed or adequately embraced by the statement of the invention in the earlier filed applications to which this application is related to satisfy the requirements set forth under 35 U.S.C. §§ 101 and/or 112, were the inventions to have been claimed in those prior applications. See M.P.E.P. §§ 201.06, 201.07, and 201.08.

This application should be redesignated as a continuation-in-part.

11. The disclosure is objected to because the disclosure refers to embedded hyperlinks and/or other forms of browser-executable code and to the Internet contents so identified. Reference to hyperlinks and/or other forms of browser-executable code

⁴ It appears the provisional application describes another nucleotide sequence that differs from the

and to the Internet contents so identified is impermissible and therefore requires deletion.

An example of such an impermissible disclosure appearing in this application is found at page 29, lines 3-6, of the specification, as filed.

The attempt to incorporate essential or non-essential subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP § 608.01(p), paragraph I regarding acceptable incorporation by reference. See 37 CFR § 1.57.

12. The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

An example of such an improperly demarcated trademark appearing in the specification is RNAzol™; see, e.g., page 27, lines 3, of the specification, as filed.

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at <http://www.uspto.gov/web/menu/search.html>.

13. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

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Claims 22-30 are drawn to a method of detecting a PCGEM1 nucleic acid in a biological sample, said method comprising combining the sample with a nucleic acid comprising at least 10 contiguous nucleotides of SEQ ID NO: 1 (claims 22 and 27-30), which method further comprises amplifying the PCGEM1 nucleic acid before said step of combining (claim 23), wherein the sample is blood, urine, or prostate tissue (claims 24-26).

The disclosure of the invention describes "detecting a PCGEM1-derived marker of prostate cancer by hybridization with an oligonucleotide probe" (paragraph [0060] of the published application) and "a method of detecting prostate cancer in a patient, which comprises (a) detecting PCGEM1 mRNA in a biological sample from the patient; and (b) correlating the amount of PCGEM1 mRNA in the sample with the presence of prostate cancer in the patient" (paragraph [0071] of the published application).

Otherwise it appears that there is no description of the claimed method, which is broadly interpreted to encompass any process that involves, or comprises the active step of detecting a PCGEM1 nucleic acid in a biological sample.

Given the striking difference between the breadth of the claims and the breadth of the only pertinent disclosures thereof, it is apparent that the claims are not limited to the subject matter that has been adequately embraced by the statement of the invention.

Accordingly, it is submitted that the disclosure, as filed, does not provide properly clear and sufficient antecedent basis for the claimed human breast cells that are not breast cancer cells.

M.P.E.P. § 608.01(o) states:

While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have clear support or antecedent basis in the specification for the new terms appearing in the claims. This is necessary in order to insure certainty in construing the claims in the light of the specification, *Ex parte Kotler*, 1901 C.D. 62, 95 O.G. 2684 (Comm'r Pat. 1901). See 37 CFR 1.75, MPEP § 608.01(i) and § 1302.01.

M.P.E.P. § 608.01(o) further states that if the examiner determines that the claims presented do not comply with 37 CFR 1.75(d)(1), applicant will be required to

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make appropriate amendment to the description to provide clear support or antecedent basis for the terms appearing in the claims provided no new matter is introduced.

In this instance, it would not be clear from a reading of the descriptive portion of this application, alone, where there is clear support or antecedent basis for the language of the claims because apart from the description of a method of detecting prostate cancer in a patient, which method comprises the step of detecting a PCGEM1 nucleic acid in a biological sample, there is no other reference to this subject matter, which is the elected invention.

Furthermore, with particular regard to the dependent claims that are drawn to the subject matter that is the elected invention, although the specification describes nucleic acid molecules (probes) comprising nucleotide sequences of varying lengths, which comprise at least 10 contiguous nucleotides of SEQ ID NO: 1 (see, e.g., paragraph [0078] of the published application), this disclosure is only fairly read in the context of a description of the non-elected invention, i.e., a method of detecting prostate cancer in a patient (see, e.g., paragraphs [0071] and [0072]). Similarly, while the specification describes a process comprising amplifying a PCGEM1 cDNA molecule, before incubating the PCGEM1 cDNA with the isolated nucleic acid of the invention and detecting hybridization between the PCGEM1 cDNA and the isolated nucleic acid, it is again only in the disclosed in the context of a description of this non-elected invention (paragraph [0071] of the published application).

Again, appropriate correction is required.

Claim Rejections - 35 USC § 101

14. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15. Claims 22-30 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The considerations that are made in determining whether a claimed invention is supported by either a specific and substantial asserted utility or a well-established utility are outlined by the published Utility Examination Guidelines (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

Briefly, a "specific and substantial" asserted utility is an asserted utility that is specific to the particular nature and substance of the claimed subject matter, and which would be immediately available for application in a "real-world" context by virtue of the existing information disclosed in the specification and/or on the basis of knowledge imparted by the prior art, such that its use would not require or constitute carrying out further research to identify or reasonably confirm its usefulness in this context. A "well-established" utility is a credible, specific, and substantial utility, which is well known, immediately apparent, and implied by the specification, and based on the disclosure of the properties of a material or subject matter, either alone or taken with the knowledge of one skilled in the art.

Claims 22-30 are drawn to a method of detecting a nucleic acid in a biological sample.

As discussed above, though these claims are deemed original claims, added by preliminary amendment filed on the same date as the application, they find inadequate antecedent basis in the disclosure of the invention.

The specification describes a process that *might* now be encompassed by the broader scope of the instant claims, but which is the subject matter of the non-elected invention encompassed by claims that have been withdrawn from further prosecution. According to claim 6 (withdrawn), this process, namely a method of detecting prostate cancer comprises the active step of detecting hybridization between a nucleic acid comprising at least 10 contiguous nucleotides of SEQ ID NO: 1 and a PCGEM1 nucleic acid molecule in a biological sample, which must effectively detect the presence of the latter in the sample.

The withdrawn claims directed to the non-elected invention find support in the disclosure of the invention at paragraph [0071] of the published application. Here, the specification discloses:

The present invention provides a method of detecting prostate cancer in a patient, which comprises (a) detecting PCGEM1 mRNA in a biological sample from the patient; and (b) correlating the amount of PCGEM1 mRNA in the sample with the presence of prostate cancer in the patient. Detecting PCGEM1 mRNA in a biological sample may include: (a) isolating RNA from said biological sample; (b) amplifying a PCGEM1 cDNA molecule; (c) incubating the PCGEM1 cDNA with the isolated nucleic acid of the invention; and (d) detecting hybridization between the PCGEM1 cDNA and the isolated nucleic acid" [underlining added for emphasis].

However, the present claims are *not* directed to a method of detecting prostate cancer, which is instead the subject matter of a non-elected invention claimed in this application; and it is only in this context of describing *the non-elected invention* that the disclosure might be interpreted as having provided a description, albeit too inadequate, of the more broadly claimed methods, which comprise the process steps recited in claims 22-30.

The present claims recite no intended use or purpose, apart from the detection of a nucleic acid in a biological sample, which amounts to no more than the acquisition of scientific data or information that might be used or applied in some specific and substantial manner, but which use or application is not part of the claimed invention. Still, because the claimed invention elicits no specific effect, nor has any particular function beyond the detection of a PCGEM1 nucleic acid in a biological sample, it is submitted that the disclosure thereof by the specification, as filed, would not make apparent *how* the invention is to be used in any manner that might be regarded both specific and substantial – if not as a mere active step, which is to be taken during the practice of the process of detecting prostate cancer, which is the subject matter of the non-elected invention.

Accordingly, it is the position of the Office that the claims are directed to an active step or perhaps a “research tool”, rather than a useful process that is practiced to achieve any particular objective or purpose that might provide immediate benefit to the public.

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Therefore, any presentation of the claims in a patent issued on the merit of those claims would amount to no more than a mere invitation to the artisan to elaborate or develop a useful process comprising the active step of detecting a PCGEM1 nucleic acid in a biological sample.

Inasmuch as the claimed invention has no requisite objective or purpose that might constitute a specific and substantial utility, such that it might be immediately practiced to the benefit to the public, the method of detecting a PCGEM1 nucleic acid in a biological sample, in and of itself, appears to have no asserted or well established utility; and the specificity and substantiality of its only putative utility *as an integral and active step of any one objective process*, nor its credibility, can be assessed.

The U.S. Supreme Court addressed the issue of utility under 35 U.S.C. § 101 in deciding *Brenner, Comr. Pats. v. Manson*, 148 U.S.P.Q. 689 (US SupCt, 1966). The Court expressed the opinion that all chemical compounds are “useful” to the chemical arts *when this term is given its broadest interpretation*; nonetheless, the court held that this broad interpretation was not the intended definition of “useful” as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed “real world” utility. The Court held that:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. *Id.*, at 695.

Further, the Court opined,

[W]e are [not] blind to the prospect that what now seems without “use” may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. *Id.*, at 696.

It is submitted the instant situation is directly analogous to that which was addressed by the Court in deciding *Brenner, Comr. Pats. v. Manson*, since hereto it might be said that all methods of detecting a nucleic acid in a biological sample are “useful” in the biochemical arts when the term is given its broadest interpretation, but nevertheless § 101 requires that an invention have either an immediately obvious or

fully disclosed "real world" utility, which the claimed invention lacks because the specification does not disclose a currently available "real world" use for the claimed method of detecting a PCGEM1 nucleic acid in a biological sample.

To employ the disclosure of the claimed method of detecting a PCGEM1 nucleic acid in a biological sample in any useful process would require further research, which should be regarded as constituting part of the inventive process. Because the specification does not disclose a currently available, "real world" use for the claimed invention, the requirements set forth under 35 U.S.C. § 101 have not been met.

To fulfill the requirements of § 101, the skilled artisan must be able to use a claimed invention in the manner asserted by Applicants' to provide some immediate benefit to the public. See Nelson v. Bowler and Crossley, 206 USPQ 881 (CCPA, 1980).

The existing information disclosed by Applicants' application would merely provide the artisan with an invitation to perform further investigations to discover how the claimed invention might be useful. Although such additional investigation might ultimately lead to a derivation of a specific benefit, an immediate benefit could not be derived from the use of the claimed invention because the existing information is insufficient to enable the artisan to use the claimed method of detecting a PCGEM1 nucleic acid in a biological sample in a specific, substantial and credible manner to provide an immediate benefit. Although the disclosure of the claimed polynucleotide might tomorrow command the grateful attention of the public, the Court has decided:

[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.

Brenner, Comr. Pats. v. Manson, 148 U.S.P.Q. 689 at 696 (US SupCt, 1966).

Claim Rejections - 35 USC § 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 22-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are too vague and indefinite to satisfy the requirement for clarity and particularity set forth under 35 U.S.C. § 112, second paragraph, for the following reasons:

The claims are directed to an omnibus subject matter, as in light of the disclosure they appear to be directed to a mere active step of which the disclosed process of detecting prostate cancer is comprised, and which is the subject matter of a non-elected invention, rather than a useful process having any one particular objective or purpose. Thus, at first glance, the claims are directed to a method of detecting a nucleic acid molecule that may conceivably be performed during any number of a vast plurality of objectively different processes.

The elected invention is a method of detecting a PCGEM1 nucleic acid in a biological sample, so the present claims are *not* directed to a method of detecting prostate cancer, which is instead the subject matter of a non-elected invention claimed in this application.

Yet, as explained above, it is only in the context of describing *the non-elected invention* that the disclosure might be interpreted as having provided a description, albeit too inadequate, of the more broadly claimed methods, which comprise the process steps recited in claims 22-30.

Moreover, inasmuch as the invention is disclosed to only this extent, the subject matter that is now claimed appears to be but a mere step in the originally disclosed process of detecting prostate cancer, which was perhaps all that Applicant originally intended to disclose, since any other contemplated use for the invention cannot be gleaned from a reading of the disclosure. Therefore, even in light of the disclosure, it is submitted the claims fail to clearly and particularly delineate the metes and bounds of the subject matter that is actually regarded as the invention, so as to permit the skilled artisan to know or readily determine infringing subject matter.

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What is the purpose or objective of practicing the invention? Why would the artisan use the invention to detect a PCGEM1 nucleic acid molecule in a biological sample? How is the scientific data or information procured by the practice of the invention necessarily used, if at all? If not a mere step in the disclosed process of detecting (diagnosing) prostate cancer, how else might Applicant intend the process, that is now claimed, be used?

To satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph, the claims *must* define the metes and bounds of the subject matter that is regarded as the invention by Applicant with the clarity and particularity necessary to permit the skilled artisan to know or determine infringing subject matter.

18. Claims 22-30 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the following reasons:

The claims are vague and indefinite because claim 1 recites, "under hybridizing conditions" without defining those conditions that are necessarily used in to practice the process, so as to determine the presence of the PCGEM1 nucleic acid in the biological sample by detecting hybridization between the PCGEM1 nucleic acid and the nucleic acid comprising at least 10 contiguous nucleotides of SEQ ID NO: 1. Formation of the hybrid, which is indicative of the presence in the sample of the PCGEM1 nucleic acid, will or will not occur, or will occur to varying extents, depending upon the conditions under which the PCGEM1 nucleic acid and the nucleic acid comprising at least 10 contiguous nucleotides of SEQ ID NO: 1 are contacted. Were those conditions relatively less "stringent", hybrid formation might occur more promiscuously, such that the nucleic acid comprising at least 10 contiguous nucleotides of SEQ ID NO: 1 might anneal (pair) with a nucleic acid molecule that would not be recognized as "a PCGEM1" nucleic acid; however, were those conditions too stringent, the nucleic acid comprising at least 10 contiguous nucleotides of SEQ ID NO: 1 might not anneal with such recognizable "PCGEM1" nucleic acids. Therefore, the hybridizing conditions effectively define the subject matter that is encompassed by the term "a PCGEM1 nucleic acid",

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thereby delineating the metes and bounds of the invention, which might be regarded as a method of detecting only nucleic acid molecules comprising the nucleotide sequence of SEQ ID NO: 1, or which might be considered a method for detecting nucleic acid molecules that are substantially unlike nucleic acid molecules comprising the nucleotide sequence of SEQ ID NO: 1.

At paragraphs [0048] and [0049] of the published application, the specification describes the different conditions that are used to define the nucleic acids that are considered members of the genus of "PCGEM1" nucleic acids to which the claims are directed. In light of this disclosure, it is apparent that the hybridizing conditions that may be used in practicing the claimed invention might vary substantially. Furthermore, it appears that the specification does not provide a standard for ascertaining the requisite degree of stringency that must be used in practicing the claimed invention. Accordingly, the "hybridizing conditions" used in practicing the claimed method may vary, such that those conditions might be highly permissive (e.g., conditions under which even very dissimilar nucleic acid molecules remain hybridized) or highly selective (e.g., conditions under which only fully complementary nucleic acid molecules remain hybridized).

As such, the metes and bounds of the subject matter that Applicant regards as the invention will vary depending upon the specific "hybridizing conditions" that are used to practice the claimed process; accordingly, the claims fail to delineate the metes and bounds of the subject matter that Applicant regards as the invention with the requisite particularity and clarity to permit the artisan to know or determine infringing subject matter, so as to satisfy the requirement set forth under 35 U.S.C. § 112, first paragraph.

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 22-30 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial

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asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The elected invention is a method of detecting a PCGEM1 nucleic acid in a biological sample, so the present claims are *not* directed to a method of detecting prostate cancer, which is instead the subject matter of a non-elected invention claimed in this application.

What is the purpose or objective of practicing the invention, apart from acquisition of scientific data or information? How is it to be used, and to what aim or objective?

As explained in the above rejection of the claims under 35 U.S.C. § 101, inasmuch as the claimed invention has no requisite objective or purpose that would be deemed specific and substantial, the invention, *in and of itself*, appears to have no apparent utility, so the sufficiency of the disclosure to reasonably enable the skilled artisan to practice the invention, or any objective process comprising the invention, as an integral and active step of that process, cannot be assessed.

Again, it is submitted that the claims would merely serve as an invitation to elaborate or develop a useful process comprising the active step of detecting a PCGEM1 nucleic acid in a biological sample. However, any need to further elaborate or develop a utility for the claimed invention would constitute a need to perform undue and/or unreasonable experimentation.

M.P.E.P. § 2164.01 states:

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

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There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors, which have been outlined in the Federal Circuit decision of *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), include, but are not limited to, the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed. See also *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

21. Claims 22-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001; hereafter "Guidelines"). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

Guidelines states:

The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not

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permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

Arguably, even if the disclosure of the invention, as filed, were to provide properly clear and sufficient antecedent basis for the claimed invention, it is aptly noted the Federal Circuit has explained that *in ipsius verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement:

Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). See also: *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, even an original claim, which necessarily provides written description for itself, may still not constitute an adequate written description of the claimed subject matter, *which establishes that the inventor was in possession of the invention*.

In this instance, claims 22-30 are directed to a process comprising detecting the presence of a PCGEM1 nucleic acid in a biological sample; however, the claimed invention achieves no requisite effect, and its use need not have any particular objective or purpose that might be deemed both specific and substantial. Rather, as explained above, the claimed invention is merely *an active step* of which some other undisclosed or unclaimed process is comprised, and which has not been described with the requisite particularity by the instant claims to satisfy the written description requirement set forth under 35 U.S.C. § 112, first paragraph.

Applicant is reminded, "generalized language may not suffice if it does not convey the detailed identity of an invention." *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Because the claimed invention has no objective or purpose, apart from the acquisition of scientific data or information concerning the presence of a PCGEM1 nucleic acid molecule, it is not possible to practice the claimed invention to achieve any one particular effect.

Accordingly, the claims would serve as a mere invitation to the artisan to develop a useful process comprising the active step of detecting a PCGEM1 nucleic acid molecule in a biological sample.

While it might be plausible, given the disclosure, to develop useful processes that achieve different objectives or purposes, which comprise the active step of detecting a PCGEM1 nucleic acid molecule in a biological sample, Applicant is reminded that the written description provision of 35 U.S.C. § 112, first paragraph, is severable from its enablement provision. An adequate written description requires more than a mere statement that it is the invention.

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (CAFC 1991). See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (CAFC 1991); *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

"Regardless whether a compound is claimed *per se* or a method is claimed that entails the use of the compound, the inventor cannot lay claim to the subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods". *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1984 (CAFC 2004).

As an additional matter, the claims are directed a method of detecting any member of a genus of "PCGEM1 nucleic acid" in any biological sample, such as, and including blood, urine, and prostate tissue. The specification describes this genus of

nucleic acid molecules as having widely varying structures, but not necessarily any particular function; see, e.g., paragraphs [0041]-[0056] of the published application. Accordingly, the claims are directed to methods of detecting any of a large plurality of structurally and/or functionally diverse nucleic acids, including but not limited to nucleic acids derived from any of numerous different species of animal, allelic variants, homologs, and nucleic acid molecules that hybridize with probes under varying degrees of stringency. Moreover, according to paragraph [0048] of the published application, the scope of this genus is so broad, as to include any variants of the particularly described molecules that might be derived by mutagenesis.

Notably, despite factual evidence that the PCGEM1 nucleic acid molecule of SEQ ID NO: 1 does not encode a protein⁵, the specification paradoxically discloses that the genus of "PCGEM1 nucleic acids" includes nucleic acids that vary from this particular molecule due to the degeneracy of the genetic code (paragraph [0048] of the published application). One cannot envision such nucleic acids, which are "degenerates" of the sequence of SEQ ID NO: 1, if the sequence does not encode a protein.

Given the fact that the members of the genus of "PCGEM1 nucleic acids" may vary so substantially, it is apparent that the specification fails to describe members of the genus as sharing any one particularly identifying structural feature, which might be correlated with any one particularly identifying functional feature that is similarly shared by at least a substantial number of those members. Consequently, the skilled artisan could not immediately envision, recognize, or distinguish at least most member of the genus; and therefore the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Guidelines states, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show

⁵ See, e.g., Srikantan et al. (*supra*); see entire document (e.g., page 12216, column 2).

that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Guidelines further states, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (*Id.* at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant had possession of the claimed invention at the time the application was filed.

Finally, the evidence of record indicates that the PCGEM1 nucleic acid of SEQ ID NO: 1 is expressed by androgen receptor-positive prostate cells, but notably none indicating that the nucleic acid, or any variant thereof, is translocated outside the prostate, such that it might be detected in biological samples, such as the blood or urine. Yet, the claims 22-24 and 26-30 are directed to a method of detecting a PCGEM1 nucleic acid in any biological sample, or more particularly in blood or urine, but not necessarily prostate tissue. Having not described the presence of any one species of PCGEM1 nucleic acid in the blood or urine, and because nucleic acid molecules are not generally translocated, or stable outside the cell, the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 22-25 and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Srikantan et al. (*Proc. Natl. Acad. Sci. USA*. 2000 Oct 24; **97** (22): 12216-12221) (of record; cited by Applicant).

Srikantan et al. teaches a nucleic acid molecule designated PCGEM1, which was detected in a biological sample (i.e., prostate tissue or cell lines derived from prostate tissue) by a process comprising contacting the sample with a nucleic acid comprising at least 10 contiguous nucleotides of SEQ ID NO: 1 under hybridizing conditions and detecting hybridization between the nucleic acid comprising at least 10 contiguous nucleotides of SEQ ID NO: 1 and the PCGEM1 nucleic acid in the sample; see entire document (e.g., page 12217, columns 1 and 2). Srikantan et al. teaches this process for detecting a PCGEM1 nucleic acid in a biological sample further comprises amplifying the PCGEM1 nucleic acid before the step of combining; see, e.g., page 12217, columns 1 and 2.

24. Claims 22-25 and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Dixon et al. (*Cancer Chemother. Pharmacol.* 1999; **43** (Suppl.): S78-S84), as evidenced by Srikantan et al. (*Proc. Natl. Acad. Sci. USA*. 2000 Oct 24; **97** (22): 12216-12221) (of record; cited by Applicant).

Srikantan et al. teaches detecting nucleic acid molecules in a biological sample (i.e., LnCaP cells, a cell line derived from cancerous prostate tissue) by a process comprising contacting the sample with a nucleic acid comprising at least 10 contiguous nucleotides of SEQ ID NO: 1 under hybridizing conditions and detecting hybridization between the nucleic acid comprising at least 10 contiguous nucleotides of SEQ ID NO:

1 and the PCGEM1 nucleic acid in the sample; see entire document (e.g., page 580, column 1).

Srikantan et al., a PCGEM1 nucleic acid is expressed by LNCaP cells; see entire document (e.g., the abstract). Therefore, as evidenced by Srikantan et al., the RNA isolated from the LNCaP cells described by Dixon et al. comprised a PCGEM1 nucleic acid (i.e., the RNA transcript of *PCGEM1*), which was used to generate a nucleic acid molecule comprising at least 10 contiguous nucleotides of SEQ ID NO: 1 that was used in the process.

Double Patenting

25. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

26. Claims 22, 23, and 27-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,828,429 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Claims 1-9 of U.S. Patent No. 6,828,429 B1 are drawn to a nucleic acid molecule that is the transcript of the *PCGEM1* gene. Having this disclosure alone would make obvious the claimed method of detecting a PCGEM1 nucleic acid in a biological sample. Basically, one would have been motivated at the time the invention was made to do so to study the expression pattern of the gene to begin to understand its function.

Conclusion

27. No claim is allowed.

28. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Srikantan et al. (*Proceedings of the American Association for Cancer Research Annual Meeting*, 1999 Mar; 40: 37) (of record; cited by Applicant) teaches the detection of a PCGEM1 nucleic acid in a biological sample.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen L. Rawlings/
Stephen L. Rawlings, Ph.D.
Primary Examiner
Art Unit 1643

slr
May 25, 2007